

Message

From: Motilall, Christina [Motilall.Christina@epa.gov]
Sent: 5/13/2020 2:10:45 PM
To: Sadowsky, Don [Sadowsky.Don@epa.gov]; Kaczmarek, Chris [Kaczmarek.Chris@epa.gov]
CC: Ingram, Earl [Ingram.Earl@epa.gov]; Mendelsohn, Mike [Mendelsohn.Mike@epa.gov]; Schwarz, Stephanie [Schwarz.Stephanie@epa.gov]
Subject: RE: Urgent: Oxitec Press Follow-Up

Hi all,

I am getting pinged on this. Any thoughts?

Best,
Christina

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 9:15 AM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: Re: Urgent: Oxitec Press Follow-Up

Christina, per the email Mike just sent, my understanding of the facts was incorrect.

Ex. 5 Attorney Client (AC)

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Wednesday, May 13, 2020 9:12 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Morning Don,

Ex. 5 Attorney Client (AC)

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 9:06 AM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>; Schwarz, Stephanie <Schwarz.Stephanie@epa.gov>
Subject: Re: Urgent: Oxitec Press Follow-Up

Good morning, Christina!

Ex. 5 Attorney Client (AC)

Does this work for you?

Don

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Wednesday, May 13, 2020 8:51 AM
To: Sadowsky, Don <Sadowsky.Don@epa.gov>; Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Morning Don,

Was drafting a message but I will shift it here! Thanks for your help on this, below is what we have:

Q: I just would like to know if the data generated under this EUP are only produced by Oxitec or if a third party is involved in the evaluation.

A.

Ex. 5 Attorney Client (AC)

Ex. 5 Attorney Client (AC)

Please review and provide your input, thank you!

Best,
Christina

From: Sadowsky, Don <Sadowsky.Don@epa.gov>
Sent: Wednesday, May 13, 2020 8:49 AM
To: Kaczmarek, Chris <Kaczmarek.Chris@epa.gov>
Cc: Motilall, Christina <Motilall.Christina@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Subject: Fw: Urgent: Oxitec Press Follow-Up

FYI, Chris.

Ex. 5 Attorney Client (AC)

I've cc'ed here some of the OPP staff working on this.

Donald A. Sadowsky
Pesticides and Toxic Substances Law Office
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
(202) 564-5638

From: Ingram, Earl <Ingram.Earl@epa.gov>
Sent: Wednesday, May 13, 2020 8:28 AM
To: Motilall, Christina <Motilall.Christina@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>; Sadowsky, Don <Sadowsky.Don@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Christina,

It's Don Sadowsky.

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Tuesday, May 12, 2020 6:17 PM
To: Ingram, Earl <Ingram.Earl@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Thanks Earl! Can you put me in touch with your OGC contact so I can have them review a potential response asap?

Best,
Christina

From: Ingram, Earl <Ingram.Earl@epa.gov>
Sent: Tuesday, May 12, 2020 4:38 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Christina,

The company made a confidentiality claim on some of that information in your response. Under the direction of OGC, I sent the company an email asking they clearly indicate the information they are claiming confidential. They have until COB tomorrow to respond. BPPD will let you know what information in your response that Oxitec is making confidentiality claims on if any.

If they do maintain claims of confidentiality, we will have them to substantiate their confidentiality claims. OGC will make the final determination on the claims. It could be a sometime before OGC makes its determination.

Earl Ingram, Chief
Public Information & Records Integrity Branch
Information Technology & Resources Management Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
(703) 305-5456

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Tuesday, May 12, 2020 4:13 PM
To: Motilall, Christina <Motilall.Christina@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>; Ingram, Earl <Ingram.Earl@epa.gov>; McBride, Sharon Y <Mcbride.Sharony@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

If not, Mike's group can help. Earl Ingram in ITRMD handles these as does Sharon McBride in ITRMD.

From: Motilall, Christina <Motilall.Christina@epa.gov>
Sent: Tuesday, May 12, 2020 4:10 PM
To: McNally, Robert <Mcnally.Robert@epa.gov>; Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>
Cc: Overstreet, Anne <overstreet.anne@epa.gov>
Subject: RE: Urgent: Oxitec Press Follow-Up

Thanks, that makes sense. I will see if we have some pre-approved language on it.

From: McNally, Robert <Mcnally.Robert@epa.gov>
Sent: Tuesday, May 12, 2020 4:08 PM
To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Motilall, Christina <Motilall.Christina@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Cc: Overstreet, Anne <overstreet.anne@epa.gov>

Subject: RE: Urgent: Oxitec Press Follow-Up

I think the answer is fine, but will likely lead to a follow-up: "What do you mean it's confidential?" The notion of confidentiality sounds suspicious to a reporter without context under the law.

We could expand with a sentence or two about how registrants are allowed to make confidentiality claims under FIFRA and what role EPA plays in refereeing that process.

From: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>

Sent: Tuesday, May 12, 2020 3:56 PM

To: Motilall, Christina <Motilall.Christina@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Cc: Overstreet, Anne <overstreet.anne@epa.gov>; McNally, Robert <McNally.Robert@epa.gov>

Subject: RE: Urgent: Oxitec Press Follow-Up

Christina,

The answer to the question below is: EPA cannot answer the question because of confidentiality claims.

Let us know if we need to discuss further. Thanks.

Eric Bohnenblust, Ph.D

Senior Biologist

Emerging Technologies Branch (ETB)

Biopesticides and Pollution Prevention Division (BPPD)

Phone: 703-347-0426

Email: Bohnenblust.eric@epa.gov

From: Motilall, Christina <Motilall.Christina@epa.gov>

Sent: Tuesday, May 12, 2020 3:45 PM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: RE: Urgent: Oxitec Press Follow-Up

Hi all,

Any word on this?

Best,

Christina

From: Motilall, Christina

Sent: Tuesday, May 12, 2020 11:59 AM

To: Bohnenblust, Eric <Bohnenblust.Eric@epa.gov>; Mendelsohn, Mike <Mendelsohn.Mike@epa.gov>

Subject: Urgent: Oxitec Press Follow-Up

Hi there,

We got a follow-up Oxitec question, in yellow, deadline is ASAP. Below the follow-up question is what we originally provided.

I just would like to know if the data generated under this EUP are only produced by Oxitec or if a third party is involved in the evaluation.

EPA previously provided:

Question 1: Why do the releases not occur within 500 meters of sewage treatment facilities and any farm producing citrus crops?

Response 1: This restriction is to ensure female OX5034 *Aedes aegypti* mosquitoes do not encounter levels of tetracycline in the environment that will result in survival of adult OX5034 female mosquitoes. Female OX5034 *Aedes aegypti* mosquitoes can survive when exposed to a high enough dose of tetracycline.

A compilation of release recapture studies around the world found that most *Ae. aegypti* mosquitoes are recovered within 20 to 50 meters of the release point, with a small percentage found at 170 meters but generally not more than 200 meters from the release point. Therefore, a restriction of 500 meters from potential sources (200 m for released OX5034 males + 200 m for mated *Ae. aegypti* females + 100 m of additional buffer) provides a conservative buffer zone to prevent OX5034 mosquitoes from encountering tetracycline in the environment. Additional detailed discussion can be found in EPA's Response to Comments in Part VI.B. in the response to comment document (document ID: EPA-HQ-OPP-2019-0274-0355).

Question 2: How are you controlling the effectiveness of the Oxitec technology?

Response 2: The purpose of the Experimental Use Permit is for Oxitec to determine the efficacy of the OX5034 *Aedes aegypti* mosquitoes for controlling populations of wild *Ae. aegypti* mosquitoes. EPA reviewed the proposed protocol to determine efficacy, thus ensuring the methods used to evaluate efficacy are appropriate and scientifically valid. EPA would evaluate the data generated under this EUP in a future application to support a product registration under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Question 3: Why does EPA decide to restrict the release (20 000 mosquito / week / acre) ?

Response 3: Oxitec proposed 20,000 adult male mosquitoes/week/acre as the maximum application rate. EPA's evaluation of the application was based on this proposed maximum application rate.

Christina Motilall (*she/her/hers*)

Acting Team Leader, Communication Services Branch

Office of Pesticide Programs

U.S. Environmental Protection Agency

Desk: (202) 564-1287 | Cell: (202) 860-5122